



2632

Dkt. 59331-AZ/JPW/MAF/AJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : James M. Binley et al.  
Serial No. : 10/032,162 Group Art Unit: 2632  
Filed : December 21, 2001  
For : STABILIZED VIRAL ENVELOPE PROTEINS AND  
USES THEREOF

1185 Avenue of the Americas  
New York, New York 10036  
February 4, 2003

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

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INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**:

1. U.S. Patent No. 5,935,579, issued to Habeshaw, J.A. et al. on August 10, 1999;
2. Atwell, S. et al. (1997) Stable Heterodimers form Remodeling the Domain Interface of a Homodimer using a Phage Display Library, J. Mol. Biol. 270: 26-35;
3. Barouch, D.H. and N.L. Letvin (2000) DNA Vaccination for HIV-1 and SIV, Intervirology. 4: 282-287;
4. Barouch, D.H. et al. (2002) Eventual AIDS Vaccine Failure in a Rhesus Monkey by Viral Escape from Cytotoxic T Lymphocytes, Nature 415: 335-339;

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Page 2

5. Burton, D.R. and J.P. Moore (1998) Why do we Not Have an HIV Vaccine and how Can we Make One? Nature Med. Vaccine Suppl. 4(5): 495-498;
6. Cao, J. et al. (1997) Replication and Neutralization of Human Immunodeficiency Virus Type 1 Lacking the V1 and V2 Variable Loops of the gp120 Envelope Glycoprotein, J. Virol. 71: 9808-9812;
7. Edinger, A.L. et al. (1999) Functional Dissection of CCR5 Coreceptor Function through the Use of CD4-Independent Simian Immunodeficiency Virus Strains, J. Virol. 73: 4062-4073;
8. Fouts, T.R. et al. (1998) Interactions of Polyclonal and Monoclonal Anti-Glycoprotein 120 Antibodies with Oligomeric Glycoprotein 120-Glycoprotein 41 Complexes of a Primary HIV Type 1 Isolate: Relationship to Neutralization, AIDS Res. Human Retrovir. 14: 591-597;
9. Fouts, T.R. et al. (1997) Neutralization of the Human Immunodeficiency Virus Type 1 Primary Isolate JR-FL by Human Monoclonal Antibodies Correlates with Antibody Binding to the Oligomeric Form of the Envelope glycoprotein Complex, J. Virol. 71: 2779-2785;
10. Gallaher, W.R. et al. (1995) A General Model for the Surface Glycoproteins of HIV and Other Retroviruses, AIDS Res. Human Retrovir. 11: 191-202;
11. Helseth, E. et al. (1991) Human Immunodeficiency Virus Type 1 gp120 envelope Glycoprotein Regions Important for

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Association with the gp41 Transmembrane Glycoprotein, J.  
Virol. 65(4): 2119-2123;

12. Haynes, B.F. (1996) HIV Vaccines: Where are we and Where are we Going? Lancet 348: 933-937;
13. Johnston, M.I. and J. Flores (2001) Progress in HIV Vaccine Development, Curr. Opin. Pharmacol. 1(5): 504-510;
14. Joy, A.K. et al. (1999) Can HIV Infection be Prevented with a Vaccine? Drugs R&D 6: 431-440;
15. Maerz, A.L. et al. (2001) Functional Analysis of the Disulfide-Bonded Loop/Chain Reversal Region of Human Immunodeficiency Virus Type 1 gp41 reveals a Critical Role in gp120-gp41 Association, J. Virol. 75(14): 6635-6644;
16. McInerney, T.L. et al. (1998) Mutation-Directed Chemical Cross-Linking of Human Immunodeficiency Virus Type 1 gp41 Oligomers, J. Virol. 72: 1523-1533;
17. Mitchell, W.M. et al. (1998) Inactivation of a Common Epitope Responsible for the Induction of Antibody-Dependent Enhancement of HIV, AIDS 12: 147-156;
18. Moore, J.P. et al. (1994a) "Probing the Structure of the Human Immunodeficiency Virus Surface Glycoprotein gp120 with a Panel of Monoclonal Antibodies, J. Virol. 68: 469-484;
19. Moore, J.P. et al. (1994b) Immunological Evidence for Interactions between the First, Second, and Fifth Conserved

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Domains to the gp120 Surface Glycoprotein of Human Immunodeficiency Virus Type 1, J. Virol. 68(11): 6836-6847;

20. Murphy, F.A. (1996) "Virus Taxonomy," in Fields Virology, Third Edition, Fields, B.N., et al. eds., Lippincott-Raven Publisher, Philadelphia, pp. 40 and 41;
21. Parren, P.W. et al. (1997) HIV-1 Antibody - Debris or Virion? Nat. Med. 3: 366-367;
22. Parren, P.W. et al. (1998) Neutralization of Human Immunodeficiency Virus Type 1 by Antibody to gp120 is Determined Primarily by Occupancy of Sites on the Virion Irrespective of Epitope Specificity," J. Virol. 72: 3512-3519;
23. Reitter, J.N. et al. (1998) A Role for Carbohydrates in Immune Evasion in AIDS, Nat. Med. 4: 679-684;
24. Schulz, T.F. et al. (1992) Conserved Structural Features in the Interaction between Retroviral Surface and Transmembrane Glycoproteins? AIDS Res. Hum. Retrovirus 8(9): 1571-1580; and
25. Stamatatos, L. et al. (1994) Differential Regulation of Cellular Tropism and Sensitivity to Soluble CD4 Neutralization by the Envelope gp120 of Human Immunodeficiency Virus Type 1, J. Virol. 68: 4973-4979.

The subject application is a divisional application of U.S. Serial No. 09/602,864, filed June 23, 2000, which in turn is a continuation-in-part of, and claims the priority date of, U.S.

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Provisional Application No. 60/141,168, filed June 25, 1999. All of the above-listed references have previously been submitted to, or cited by, the U.S. Patent and Trademark Office in an application relied upon by the subject application for an earlier effective filing date. Specifically, references 1, 16, 17, and 25 were submitted to the Patent Office in a Supplemental Information Disclosure Statement filed November 30, 2000 in connection with U.S. Serial No. 09/602,864. References 2, 6-10, 18, and 21-24 were submitted to and considered by the Patent Office in an Information Disclosure Statement filed September 13, 2000 in connection with U.S. Serial No. 09/602,864. References 3, 4, 5, 11-15, 17-19, 20 and 23 were previously cited by the U.S. Patent and Trademark Office in an Office Action issued on March 1, 2002 in connection with U.S. Serial No. 09/602,864. Accordingly, pursuant to 37 C.F.R. §1.98(d), copies of these references are not required to be provided to the Patent Office since they were previously cited by, or submitted to, the Patent Office in an application relied upon for an earlier effective filing date under 35 U.S.C. §120.

PCT International Application No. PCT/US00/17267, filed June 23, 2000, is a foreign counterpart of U.S. Serial No. 09/602,864. An International Search Report was issued on September 7, 2000 in connection with PCT International Application No. PCT/US00/17267. A copy of this Search Report is attached hereto as **Exhibit B**. All the references cited therein have been previously cited in the September 13, 2000 Information Disclosure Statement or the November 30, 2000 Supplemental Information Disclosure Statement in U.S. Serial No. 09/602,864.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned

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attorneys invite the Examiner to telephone at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

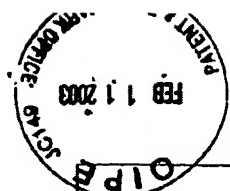
Respectfully submitted,

*Mark A. Farley*

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents,  
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<b>Form PTO-1449</b>		<b>U.S. Department of Commerce Patent and Trademark Office</b>		<b>Atty. Docket No.</b> 59331-AZ /JPW/MAF/AJD		<b>Serial No.</b> 10/032,162							
<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)				<b>Applicant(s)</b> James L. Binley et al.									
				<b>Filing Date</b> December 21, 2001		<b>Group Art Unit</b> 2632							
<b>U.S. PATENT DOCUMENTS</b>													
<b>Examiner Initials</b>		<b>Document Number</b>		<b>Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>	<b>Filing Date If Appropriate</b>					
		5	9	3	5	5	7	9	08/10/99	Habeshaw, J.A. et al.			
<b>FOREIGN PATENT DOCUMENTS</b>													
		<b>Document Number</b>		<b>Date</b>	<b>Country</b>	<b>Class</b>	<b>Subclass</b>	<b>Translation</b>					
								<b>Yes</b>	<b>No</b>				
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>													
		Atwell, S. et al. (1997) Stable Heterodimers form Remodeling the Domain Interface of a Homodimer using a Phage Display Library, J. Mol. Biol. 270: 26-35;											
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<b>EXAMINER</b>					<b>DATE CONSIDERED</b>								
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		Haynes, B.F. (1996) HIV Vaccines: Where are we and Where are we Going? Lancet 348: 933-937;		
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		Mitchell, W.M. et al. (1998) Inactivation of a Common Epitope Responsible for the Induction of Antibody-Dependent Enhancement of HIV, AIDS 12: 147-156;		
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		Moore, J.P. et al. (1994b) Immunological Evidence for Interactions between the First, Second, and Fifth Conserved Domains to the gp120 Surface Glycoprotein of Human Immunodeficiency Virus Type 1, J. Virol. 68(11): 6836-6847;		
		Murphy, F.A. (1996) "Virus Taxonomy," in Fields Virology, Third Edition, Fields, B.N., et al. eds., Lippincott-Raven Publisher, Philadelphia, pp. 40 and 41;		
		Parren, P.W. et al. (1997) HIV-1 Antibody - Debris or Virion? Nat. Med. 3: 366-367;		
		Parren, P.W. et al. (1998) Neutralization of Human Immunodeficiency Virus Type 1 by Antibody to gp120 is Determined Primarily by Occupancy of Sites on the Virion Irrespective of Epitope Specificity," J. Virol. 72: 3512-3519;		
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		Schulz, T.F. et al. (1992) Conserved Structural Features in the Interaction between Retroviral Surface and Transmembrane Glycoproteins? AIDS Res. Hum. Retrovirus 8(9): 1571-1580; and		
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